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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,195	09/14/2001	Martin John Glenton Hughes	GJE-71	7256

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SALIWANCHIK LLOYD & SALIWANCHIK  
A PROFESSIONAL ASSOCIATION  
PO BOX 142950  
GAINESVILLE, FL 32614-2950

EXAMINER

DUFFY, PATRICIA ANN

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 09/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/868,195

Applicant(s)

HUGHES ET AL.

Examiner

Patricia A. Duffy

Art Unit

1645

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 18 July 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 25,27,28,32,36,45 and 47-51 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 45 and 47 is/are allowed.
- 6) ☒ Claim(s) 25,27,28,32,36 and 48-51 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7-18-05 has been entered.

The amendment filed 7-18-05 has been entered into the record. Claims 1-24, 26, 29-31, 33-35, 37-44 and 46 have been cancelled. Claims 25, 27, 28, 32, 36, 45 and 47-51 are pending and under examination.

The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

***Rejections Withdrawn***

The rejection of claims 25, 27, 28, 32-46 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is withdrawn in view of the amendments to the claims.

The rejection of claims 45 and 46 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is withdrawn in view of Applicants pointing to the specification by page and line number where specific written description for the claimed invention resides.

*Rejections Maintained*

Claims 25, 27, 28, 32, 36 and 48-51 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is maintained for reasons made of record for claims 25-29 in the Office Action mailed 4-21-04 and in the Final Rejection mailed 1-14-05.

Applicants' arguments have been carefully considered but are not persuasive. Applicants indicate that the protein used in the experiments described in the Moore Declaration of record with the polypeptide of SEQ ID NO: 12, a non-phosphorylating NADP-dependent glyceraldehyde-3-phosphate dehydrogenase. This is not persuasive, the declaration does not attest to this fact. Representative's assertions cannot take the place of a properly executed declaration. Applicants argue that the teachings of the specification must be taken as true unless the Patent Office can cite specific reasons to doubt the asserted truth thereof. This is not persuasive, as set forth in the first office action mailed 4-21-04, the examiner cited a plethora of evidence and scientific reasoning as to why the invention was not enabled at the time the invention was filed. The invention must be enabled at the time that the invention was filed. The specification critically lacked the showings of the declaration. The specification lacked any evidence of efficacy or treatment using the isolated protein at the time that the invention was made (MPEP 2164.05(a)). Applicants argue that the presence or absence of working examples is not determinative on enablement. This is not persuasive, in highly unpredictable fields of endeavor, such as vaccine and therapeutics, the presence or absence of working examples is a factor taken into account in reaching a conclusion of undue experimentation. In reaching a conclusion of undue experimentation, the following factors were considered: quantity of experimentation necessary, amount of direction or guidance presented, the

presence or absence of working examples, the nature of the invention, the state of the prior art, relative skill of those in the art, the predictability or unpredictability of the art and the breadth of the claims (*In re Wands* (CAFC) 8 USPQ2d 1400). Applicants argue that the Declaration was filed to indicate that the specification as filed was enabled at the time of filing. This is not persuasive; the deficiencies of the Moore declaration have been extensively addressed in the final office action of 1-14-05. The declaration does not address the claimed invention in relation to local or urinary tract infections. Applicant's assertions of what the declaration addresses are insufficient to obviate the rejection for reasons made of record and that the declaration does not attest to the facts asserted by Applicants representative. Critical to enable the vaccine at the time of invention was filed is a demonstration of protection. The art at the time that the invention was made the art did not teach any other similar proteins that were protective and in the absence of a showing of protection at the time that the invention was made, the skilled artisan would have reason to doubt that the protein would be effective. The specification merely invites the skilled artisan into further experimentation to ascertain if the protein is protective or not.

The rejection is maintained.

#### ***New Rejections Based on Amendment***

Claims 50 and 51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claims 50 and 51, the claims require that the patient be a neonate and as depending from claim 25 it would require that the neonate be administered the non-phosphorylating NADP-dependent glyceraldehyde-3-phosphate dehydrogenase. However, the dependent claims 50 and 51 apparently redefine the subject that is administered. Therefore, the claims are confusing in the structure because the patient to be

administered is a neonate, but the administration is redefined as the mother of the neonate. As such, the dependent claims are in conflict with the parent claim in view of the recited antecedent basis for "the patient".

### *Status of Claims*

Claims 45 and 47 are allowed. Claims 25, 27, 28, 32, 36 and 48-51 stand rejected.

### *Conclusion*

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 571-272-0855. The examiner can generally be reached on M-Th 6:30 am - 6:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patricia A. Duffy  
Primary Examiner  
Art Unit 1645

*Patricia A. Duffy*  
PATRICIA A. DUFFY  
PRIMARY EXAMINER